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Single implants with different neck designs in the aesthetic zone: a randomized clinical trial

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Abstract

Objectives: To compare single implants in the aesthetic zone with different neck designs for marginal bone-level changes and clinical outcome measures.

Materials and methods: Ninety-three patients with a missing anterior tooth in the maxilla were randomly assigned to be treated with an implant with a 1.5 mm smooth neck ("smooth group"), a moderately rough neck with grooves ("rough group") or a scalloped moderately rough neck with grooves ("scalloped-group"). Implants were installed in healed sites and were loaded after 3 months. Follow-up visits were conducted at 6 and 18 months after implant placement.

Results: The scalloped group showed significantly more radiographic bone loss from implant placement to 18 months (2.01 ± 0.77 mm) compared with the smooth group (1.19 ± 0.82 mm) and rough group (0.9 ± 0.57 mm). Furthermore the scalloped group showed significantly deeper pocket depths and a higher bleeding score. There were no between-group differences in soft tissue levels. Survival rates were 97% for the smooth group and 100% for the rough and scalloped groups ($P > 0.05$). No significant differences in outcome were found between the smooth group and rough group.

Conclusion: For anterior tooth replacements, implants with a scalloped neck showed more marginal bone loss and less favourable clinical outcome compared with implants with a 1.5 mm smooth neck or implants with a rough neck.

A lost or congenitally missing tooth in the anterior region usually requires prosthetic replacement for functional and aesthetic reasons. The aesthetic outcome is determined by the appearance of the crown and the surrounding soft tissues, which should be harmonious with the adjacent dentition.

Currently, dental implants are widely used for dental rehabilitation, even in aesthetically delicate areas as the anterior maxilla. The level of the peri-implant marginal bone is strongly related to the level of the peri-implant mucosa (Bengazi et al. 1996; Hermann et al. 1997, 2000, 2001; Chang et al. 1999) which, in turn, is commonly considered a major factor determining the aesthetic outcome (Furhauser et al. 2005; Meijer et al. 2005). Loss of peri-implant marginal bone could therefore affect the level of the peri-implant mucosa, and hence, the final aesthetic outcome. Furthermore, marginal bone loss may induce pocket formation, which could be unfavourable for the long-term health of the peri-implant tissues (Rams et al. 1984; Heydenrijk et al. 2002).

There is evidence that the design of the implant neck influences the amount of marginal peri-implant bone loss (Shin et al. 2006; Lee et al. 2007; McAllister 2007; Bratu et al. 2009; Nickenig et al. 2009). Although the traditional smooth implant neck is accompanied by the least accumulation of plaque (Teughels et al. 2006; Baldi et al. 2009), several studies have shown more marginal bone loss around these implants compared with implants with a rough surface topography at the implant neck (Shin et al. 2006; Bratu et al. 2009; Nickenig et al. 2009). Furthermore, it has been reported that retention elements at the implant neck, such as grooves or microthreads, favour the preservation of marginal bone (Palmer et al. 2000; Shin et al. 2006; Lee et al. 2007). In addition, it has been suggested that an implant neck with a scalloped implant platform might preserve proximal marginal bone (Wohrle 2003; Kan et al. 2007; McAllister 2007). A scalloped implant neck would mirror the natural alveolar ridge curvature, particularly in the anterior zone, and consequently a more

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non-violent position of the implant–abutment interface could be realized compared with common flat-platform implant designs.

There is however, a paucity of well-designed trials addressing the influence of the implant neck design on bone and soft tissue parameters in single-implant cases in the aesthetic zone (den Hartog et al. 2008). Therefore, the main objective of our study was to compare the marginal bone level change around single implants in the maxillary aesthetic zone with a 1.5 mm smooth neck, a moderately rough neck with grooves and a scalloped moderately rough neck with grooves. In addition, the influence of the implant neck architecture on soft tissue levels and clinical outcome variables was taken into consideration.

Material and methods

Patients

Patients referred to the department of Oral and Maxillofacial Surgery (University Medical Center Groningen, University of Groningen, Groningen, the Netherlands) for single-implant treatment in the maxillary anterior region were considered for inclusion if they fulfilled the following criteria:

- at least 18 years of age;
- one missing tooth being an incisor, canine or first premolar in the maxilla with adjacent natural teeth;
- adequate oral hygiene, i.e. modified plaque index score and modified sulcus bleeding index score ≤ 1 (Mombelli et al. 1987);
- mesial–distal width of diastema at least 6 mm.

Exclusion criteria were:

- ASA score \geq III (Smeets et al. 1998);

- presence of clinically active periodontal disease as expressed by probing pocket depths ≥ 4 mm and bleeding on probing (index score > 1);
- presence of peri-apical lesions or any other abnormalities in the anterior region as detected on a radiograph;
- smoking;
- a history of radiotherapy to the head and neck region.

Study design

This prospective, randomized clinical trial was approved by the Medical Ethical Committee of the University Medical Center Groningen. Patients were included between January 2005 and February 2008. A written informed consent was obtained from all eligible patients before enrolment.

A specifically designed locked computer software program was used to randomly assign patients to one of three study groups to be treated with:

- a 1.5 mm smooth (“machined”) implant neck (Replace Select Tapered, Nobel Biocare AB, Göteborg, Sweden) – “smooth group” (Fig. 1a);
- a moderately rough implant neck with grooves (NobelReplace Tapered Groovy, Nobel Biocare AB) – “rough group” (Fig. 1b);
- a scalloped moderately rough implant neck with grooves (NobelPerfect Groovy, Nobel Biocare AB) – “scalloped group” (Fig. 1c).

Randomization by minimization (Altman 1991) was used to balance possible prognostic variables between the three treatment groups. Minimization was used for the variables age (≤ 30 , $> 31 \leq 60$, > 60 years), location of the

implant site (central or lateral incisor, canine or first premolar) and whether or not a pre-implant augmentation procedure was indicated based on a clinical and diagnostic cast assessment. The allocation result was kept in a locked computer file that was not accessible for the examiner and the practitioners. The surgeon who inserted the implants was informed about the allocation on the day of surgery.

Intervention procedure

All implants were placed in healed sites. A minimal period of 3 months after tooth removal was adopted allowing the extraction site to heal. When bone volume was insufficient for implant placement, a bone augmentation procedure was carried out. As a grafting material, autogenous bone from the retromolar-ramus or maxillary tuberosity area was used together with anorganic bovine bone (Geistlich Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland) covered with a Geistlich Bio-Gide membrane (Geistlich Pharma AG). Implants were inserted 3 months after the augmentation procedure.

One day before implant surgery, patients started taking antibiotics (amoxicillin 500 mg, three times daily for 7 days or clindamycin 300 mg, four times daily for 7 days in case of amoxicillin allergy) and using a 0.2% chlorhexidine mouthwash (two times daily for 7 days) for oral disinfection. Following local anaesthesia, a slightly palatal crest-incision was made with extensions through the buccal and palatal sulcus of the adjacent teeth and a divergent relieving incision at the distal tooth. A minimal mucoperiosteal flap was prepared to expose the alveolar ridge. The implant site was prepared by using a surgical template that was fabricated in the dental laboratory, based on the prospective implant

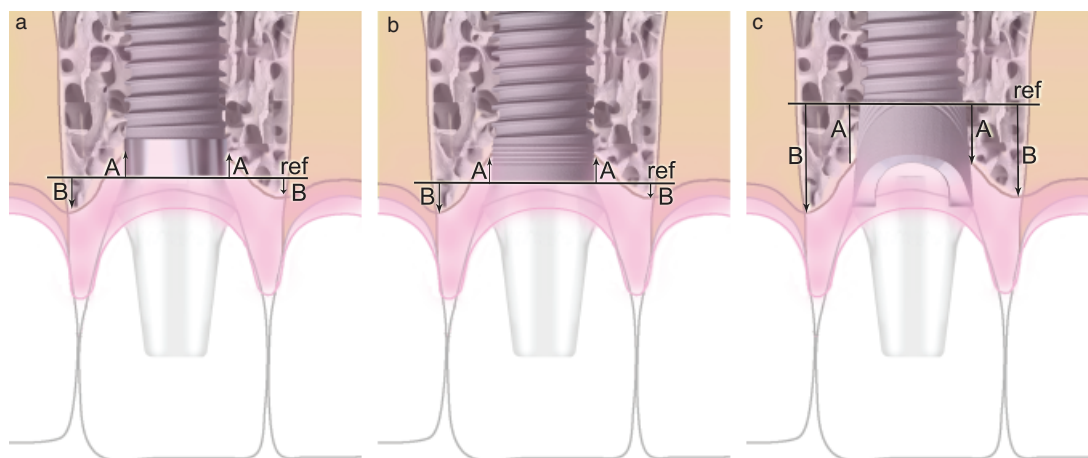


Fig. 1. (a) 1.5 mm smooth implant neck (Replace Select Tapered, Nobel Biocare AB). (b) Moderately rough implant neck with grooves (NobelReplace Tapered Groovy, Nobel Biocare AB). (c) Scalloped moderately rough implant neck with grooves (NobelPerfect Groovy, Nobel Biocare AB). Abbreviations for (a–c): ref, reference line. A and B, distances from reference line to marginal bone levels of implant and adjacent teeth.

crown in its ideal position. All implants were installed with a torque controller (OsseCare, Nobel Biocare AB) adjusted to an insertion torque of 45 N cm and by using a manual torque wrench (Nobel Biocare AB) for fine-tuning of the implant depth. The shoulder of the implant was placed at a depth of 3 mm apical to the most facial and cervical aspect of the prospective clinical crown for proper emergence profile. For the scalloped implants, the mid-facial part of the implant shoulder was taken as a reference. In all cases, the alveolar bone was levelled to the implant neck. When part of the implant remained uncovered or when the bone wall thickness facially to the implant was < 2 mm, a local augmentation procedure was performed with autogenous bone chips collected during implant bed preparation and anorganic bovine bone (Geistlich Bio-Oss) covered with Geistlich Bio-Gide. The wound was closed with Ethilon 5-0 nylon sutures (Johnson & Johnson Gateway, Piscataway, NJ, USA). During the healing phase, patients were wearing a removable partial denture that did not interfere with the wound. After 3 months, implants were uncovered and a healing abutment (Nobel Biocare AB) was installed.

One week after the second-stage operation, an implant-level impression was made. In the dental laboratory, a screw-retained provisional crown was fabricated by means of an engaging temporary abutment and composite (Solidex, Shofu Inc., Kyoto, Japan). The provisional crowns were screwed directly onto the implant with 32 N cm as indicated by a manual torque wrench (Nobel Biocare AB). After a provisional phase of 3 months (i.e., 6 months post-implant placement), a final impression was taken on implant level. In the laboratory, a waxing of the definitive crown was made that was cut back to the desired form of the abutment. The wax-up was scanned to retrieve individualized zirconia abutments (Procera, Nobel Biocare AB) for the implants in the smooth group and rough group and individualized titanium abutments (NobelProcera, Nobel Biocare AB) for the implants in the scalloped group, because zirconia abutments were not available for these implants. A zirconia Procera coping (Procera, Nobel Biocare AB) was luted over the titanium abutments in order to create an abutment with a zirconia outside. Depending on the location of the screw access hole, the final crown was either cement-retained using a zirconia coping (Procera, Nobel Biocare AB) or screw-retained by fusing porcelain directly to the abutment. Abutment screws were torqued with 32 N cm. Cement-retained crowns were cemented with glass ionomer cement (Fuji Plus, GC Europe, Leuven, Belgium). For more details regarding product specifications, we refer to a previous clinical report (den Hartog et al. 2009).

All surgical procedures were performed by a single experienced oral and maxillofacial surgeon (G.M.R.). The prosthetic procedure was accomplished by two experienced prosthodontists (H.J.A.M., K.S.), and all crowns were fabricated by one dental technician (H.S.).

Outcome measures

The primary outcome measure of this study was marginal bone-level change proximal to the implant 18 months after implant placement measured on radiographs.

Secondary outcome measures were implant survival, change in peri-implant mucosal level (PML) and its position compared with the gingival level of the contralateral tooth, papilla volume (papilla index), amount of plaque (plaque index), bleeding after probing (bleeding index) and probing pocket depth. In addition to the implant, the adjacent teeth were also analysed. The operationalization of variables is described below.

Radiographic and photographic assessments

After implant placement (baseline, T_0) and after 6 (T_{6m} , after definitive crown placement, equals 3 months of functional loading) and 18 months (T_{18m} , equals 12 months after definitive crown placement and 15 months of functional loading), standardized digital intra-oral radiographs were taken according to a long-cone paralleling technique and with a device as described by Meijndert et al. (2004). The same device was used to gather standardized digital photographs (camera: Fuji-film FinePix S3 Pro) before implant placement (T_{pre}) and at T_{6m} and T_{18m} , together with digital photographs of the implant and contralateral tooth at T_{18m} taken with the same camera. For calibration of the photographs, a calibrated probe was held in close contact and parallel to the long axis of a tooth adjacent to the implant. By using the same device, both the radiographs and the photographs were taken from the same horizontal and vertical angulation. All measurements were performed by one examiner (L.H.) and were blinded for the photographs. The radiographic examination could not be blinded, because the type of implant neck could be derived directly from the radiographs. Full-screen analysis of the radiographs was performed using specifically designed software. First, the radiographs were calibrated according to the known diameter of the implant. Next, different reference lines were drawn (Fig. 1a–c). For the implants in the smooth and rough group, the implant–abutment interface was used as a reference line (Fig. 1a and b). For the scalloped implants, the apical corners of the implant collar were used to draw a reference line (Fig. 1c), because the implant–abutment interface of the scalloped implants cannot be detected

easily and reproducibly on radiographs. After reference lines were drawn, marginal bone levels proximal to the implant were measured according to the first bone-to-implant contact together with marginal bone levels of the adjacent teeth (Fig. 1a–c). Full-screen analysis of the photographs was performed using Adobe Photoshop (Adobe Photoshop CS3 Extended, Adobe Systems Inc., San Jose, CA, USA). After calibration, mid-facial mucosal and papilla levels of the implant were measured after definitive crown placement (from T_{6m}). Mid-facial gingival levels of the adjacent teeth were measured from T_{pre} . The incisal edges of the implant crown and adjacent teeth were used as a reference.

To assess the reliability of the radiographic and photographic examinations, 14 radiographs and 14 photographs from each study group (i.e., 15% of all radiographs and photographs) were randomly selected and were measured by two examiners (L.H., N.T.) and by one examiner (L.H.) twice with a 2-week interval. The intra-observer agreement of the photographic examination was tested earlier and reported as good with a mean difference of 0.11 ± 0.02 mm between both times of measurements (Meijndert et al. 2004). The facial PML was compared with the gingival level of the contralateral tooth on photographs taken at T_{18m} and was judged as follows: identical level; slight deviation < 1.5 mm; and major deviation ≥ 1.5 mm. An acceptable reliability of this method was reported in earlier studies (Gehrke et al. 2008).

Clinical assessments

Before implant placement (T_{pre}) and 6 (T_{6m}) and 18 months after implant placement (T_{18m}), patients were seen for clinical data collection. Both the implant and the adjacent teeth were analysed at the facial aspect. All data were retrieved by one blinded examiner (L.H.) according to a specified protocol. The following variables were evaluated:

- *Plaque*, using the modified plaque index (Mombelli et al. 1987): 0 = no detection of plaque, 1 = plaque can be detected by running a probe across the surface of the crown, 2 = plaque visible with the naked eye, and 3 = abundance of plaque.
- *Bleeding*, using the modified sulcus bleeding index (Mombelli et al. 1987): 0 = no bleeding running a periodontal probe along the sulcus, 1 = isolated bleeding spots visible, 2 = a confluent red line of blood along the gingival margin, and 3 = profuse bleeding.
- *Volume of the inter-proximal papilla*, using the papilla index (Jemt 1997): 0 = no papilla, 1 = less than half of the papilla fills up the proximal space, 2 = at least half of the papilla is present but not all the way up to the

- contact point, 3 = papilla fills up the entire proximal space, and 4 = papilla is hyperplastic.
- *Probing pocket depth.* The probing pocket depths were measured to the nearest 1 mm using a manual periodontal probe (Williams Color-Coded Probe, Hu-Friedy, Chicago, IL, USA) at the mesio-facial, mid-facial and disto-facial aspects of the implant crown and adjacent teeth.

During follow-up, implant survival was registered (defined as the existence of an implant in the oral cavity [Laney 2007]).

Data analysis

Sample size was calculated using G*power version 3.1 (Faul et al. 2009). We considered 0.5 mm of radiographic marginal bone loss from implant placement to 18 months thereafter, as a relevant difference between study groups. With an expected standard deviation of 0.6 mm as derived from the literature (den Hartog et al. 2008), a two-sided significance level of 5% and a power of 90%, a minimum of 81 patients would be required (i.e., 27 per group). To deal with a withdrawal, the minimum number of patients per group was set at 31.

The intra- and inter-observer agreement for the radiographic and photographic assessments were expressed as the 95% limits of agreement (Altman 1991), representing the interval containing 95% of the differences between the observations to be compared. In addition, intra-class correlation coefficients were calculated.

For between-group comparisons of numeric and normally distributed variables (assessed with visual tests using Q-Q plots and Kolmogorov-Smirnov tests), one-way analyses of variance (ANOVA) were conducted, followed by post-hoc multiple comparison tests (Tukey's test) in case of statistical significance. For pairwise within-group comparisons, *t*-tests for matched samples were used. Qualitative variables and numeric variables that were not normally distributed were statistically explored with Kruskal-Wallis tests for between-group comparisons and Mann-Whitney tests to compare two independent conditions. Friedman's tests and Wilcoxon's signed-rank tests were applied for more-than-two within-group comparisons and to compare two dependent conditions, respectively. A Bonferroni correction was used to control the Type I error.

A multivariate linear regression analysis was performed to identify potential predictive factors for the primary outcome of change in marginal bone level from baseline (T_0) to T_{18m} . The following predictors were entered using a block-wise entry procedure: type of implant, augmentation before implant surgery, implant-tooth

distance, implant site (I1/I2/C/P1), type of definitive implant crown (screw- or cement-retained), age and gender. Pearson's and Spearman's correlations were used to explore possible significant relationships between marginal bone level change from T_0 to T_{18m} and the secondary outcome measures.

In all analyses, a significant level of 0.05 was chosen. Data were analysed using the Statistical Package for Social Sciences (version 16.0, SPSS Inc., Chicago, IL, USA).

Results

Patients

A total of 93 patients were allocated to the study groups of this trial (Table 1). Most of the missing teeth had a history of trauma. All implants could be inserted with good primary stability (>45 N cm). Details about the surgical and prosthetic procedures applied in the various treatment groups are depicted in Table 1. In two patients (one in the smooth group and one in the scalloped group), a pre-implant augmentation procedure, which was not indicated beforehand, appeared to be necessary during implant surgery and the implants were inserted 3 months later. All patients attended the follow-up visits at T_{18m} . One patient in the scalloped group did not attend the recall visit at T_{6m} .

Reliability of radiographic and photographic assessments

The assessment of the intra-observer agreement of the radiographic examination, revealed a mean difference between the repeated measurements of -0.01 ± 0.25 mm (limits of agreement: -0.5 and 0.5 mm). A difference in the range of -0.2 to 0.2 mm was found in 70.7% of the measurements and a difference in the range of -0.5 to 0.5 mm in 92.8% of the measurements (we

considered 0.5 mm as a relevant difference in our power analysis). The assessments of the radiographic and photographic inter-observer agreement, showed mean differences between the observers of 0.08 ± 0.31 mm for the radiographs (limits of agreement: -0.69 and 0.54 mm) and -0.02 ± 0.18 mm for the photographs (limits of agreement: -0.38 and 0.34 mm). For the radiographs, an inter-observer difference in the range of -0.2 to 0.2 mm and in the range of -0.5 to 0.5 mm was found in 54.2% and 89.5% of the measurements, respectively. For the photographs, these percentages were 83.5% and 96.1%.

The intra-class correlation coefficients were 0.96 and 0.99 for the radiographic inter- and intra-observer agreement, respectively, and 0.99 for the photographic inter-observer agreement, all signifying high levels of agreement.

Change in marginal bone level

The total amount of mean marginal bone loss (mesial and distal implant sides combined) between baseline (T_0 , implant placement) and T_{18m} (18 months after implant placement) was 1.19 ± 0.82 mm in the smooth group (95% confidence interval [CI]: $0.89-1.49$), 0.9 ± 0.57 mm in the rough group (95% CI: $0.7-1.1$) and 2.01 ± 0.77 mm in the scalloped group (95% CI: $1.74-2.28$) and was significantly different (ANOVA, $P < 0.001$) (Fig. 2). The scalloped group showed more marginal bone loss from T_0 to T_{18m} at both proximal implant sides compared with the smooth group (Tukey's test, $P < 0.05$) and rough group (Tukey's test, $P < 0.001$) (Table 2). There were no significant differences between the smooth and rough study groups. The most extensive marginal bone loss was observed during the first evaluation period (from T_0 to T_{6m} , mesial and distal sides combined: smooth group 1.05 ± 0.69 , rough group

Table 1. Baseline characteristics and treatment specifications per study group

Variable	Smooth group (n = 31)	Rough group (n = 31)	Scalloped group (n = 31)
Mean age \pm SD (range)	37.2 \pm 12.9 (18–60)	40.1 \pm 14.4 (18–67)	40.1 \pm 17.2 (19–80)
Male/female ratio	15/16	17/14	14/17
Implant site location I1/I2/C/P1	20/7/1/3	18/8/3/2	18/6/3/4
Cause of tooth loss			
Fracture (crown or root)	19	15	21
Agenesis	3	4	3
Endodontic failure	2	8	2
Periodontal failure	1	2	2
Root resorption	6	2	3
Augmentation before implant surgery*	12	11	10
Implant-tooth distance (mm)			
Mean \pm SD	2.36 \pm 0.76	2.17 \pm 0.77	2.30 \pm 0.65
Range	0.7–4.59	0.45–5.26	0.56 \pm 5.15
Type of final restoration			
Screw-retained	15	12	11
Cement-retained	14	19	20

*Implant was placed 3 months later.

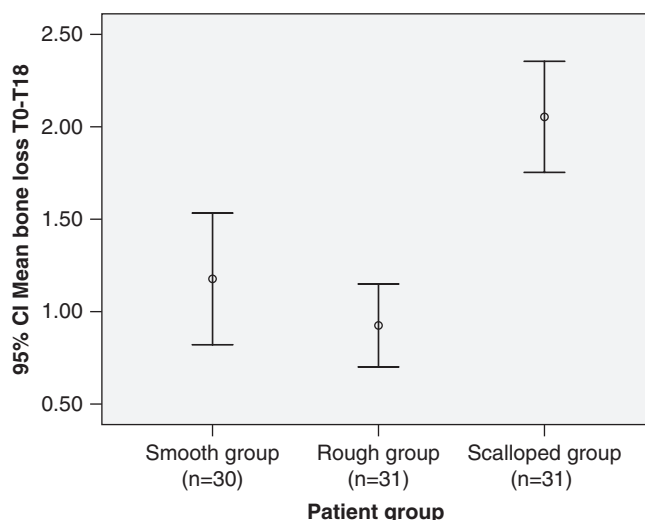


Fig. 2. Error plot of marginal bone loss from implant placement to 18 months thereafter.

0.80 ± 0.57 , scalloped group 1.77 ± 0.82) and was significantly lower for the second evaluation period (from T_{6m} to T_{18m} : smooth group 0.13 ± 0.31 , rough group 0.11 ± 0.28 , scalloped group 0.23 ± 0.43) (t -test, $P < 0.001$).

Marginal bone loss at the adjacent teeth was limited, and there were no significant differences between the study groups.

Clinical outcomes

One implant in the smooth group was lost 5 months after implant placement during the provisional phase. The implant survival rate at T_{18m} was 96.8% for the smooth group and 100% for the rough and scalloped study groups.

The photographic assessments did not yield between-group differences in mid-facial PMLs and papilla levels during follow-up (Table 2). After definitive crown placement, the level of the mid-facial peri-implant mucosa remained stable, while a gain in papilla height was observed (Table 2). The mid-facial gingival level of the adjacent teeth showed a mean recession of 0.18 ± 0.45 , 0.28 ± 0.36 and 0.25 ± 0.29 mm in the smooth, rough and scalloped groups, respectively. It appeared that the level of the PML was identical to the contralateral tooth in 14 cases (48%) in the smooth group, 13 (42%) in the rough group and 18 (58%) in the scalloped group. A major discrepancy (≥ 1.5 mm) was found in four cases (14%) in the smooth group, four in the rough group (13%) and two in the scalloped group (6%). Differences were not significant.

Between-group analyses showed significant differences for probing pocket depths at T_{18m} at all sides (Kruskal–Wallis test, $P < 0.001$ at proximal sides, $P < 0.05$ mid-facially) and mesially at T_{6m} ($P < 0.05$) (Table 2). Post-hoc analyses using Mann–Whitney tests revealed higher probing

pocket depths in the scalloped group at T_{18m} compared with the smooth group (mid-facial sides $P < 0.05$, proximal sides $P < 0.001$) and compared with the rough group at both proximal sides ($P < 0.05$). At T_{6m} , mesially deeper probing pocket depths were found in the scalloped group compared to the rough group ($P < 0.05$).

Bleeding index scores were higher for the scalloped group at T_{18m} compared with the rough and smooth group (Mann–Whitney test, $P < 0.05$, Fig. 3). There were no between-group differences in plaque scores and papilla index scores (Fig. 4) at both follow-up examinations and no differences in bleeding scores at T_{6m} . Plaque index scores were low at both follow-up visits. At T_{18m} , a plaque score of 1 was assigned to one implant in the smooth group and three implants in the other study groups. All other implants did not show any plaque. With regard to between-group comparisons of the adjacent teeth, no differences in clinical outcomes were found. Bleeding index scores of the adjacent teeth were significantly lower compared with the scores of the implants (Wilcoxon's signed-rank test, $P < 0.01$).

Within-group analyses using Wilcoxon's signed-rank tests showed that the volume of the papillae, expressed in papilla index scores, increased significantly during follow-up (smooth implants, both papillae, $P < 0.05$; rough implants, distal papillae $P < 0.05$; scalloped implants, distal papillae, $P < 0.05$) (Fig. 4). The scalloped implants showed significantly higher bleeding index scores at T_{18m} compared with T_{6m} ($P < 0.001$). The adjacent teeth showed higher plaque scores at T_{pre} vs. T_{6m} and T_{18m} ($P < 0.05$).

Regression and correlation analysis

The regression analysis revealed that only the type of implant neck was significantly associated

with the change in marginal bone level (Table 3). The other independent variables did not contribute significantly. The implant site could not be included in the analysis, because there were not enough cases in which a tooth other than a central incisor was replaced. The correlation analysis showed that the amount of marginal bone loss at both proximal sides was positively related to probing pocket depth at that side (correlation coefficient mesial side 0.27; distal side 0.32). Furthermore, the total amount of marginal bone loss (mesial and distal sides combined) was positively correlated to probing pocket depth mid-facially with a coefficient of 0.34. No other significant correlations were found.

Discussion

This study compared the effect of three different implant neck designs on preservation of marginal bone for single implants in the maxillary aesthetic zone. Implants had a 1.5 mm smooth implant neck ("smooth group"), a moderately rough implant neck with grooves ("rough group") and a scalloped moderately rough implant neck with grooves ("scalloped group"). The results of our study showed that after 18 months of follow-up, there was a significant difference in radiographic marginal bone loss between the study groups that could entirely be attributed to the scalloped group. In addition to more bone loss, the scalloped group revealed deeper probing pocket depths and higher bleeding scores than the smooth group and rough group. Post-hoc analyses did not reveal significant differences in outcome between the smooth group and rough group. The smooth and rough group revealed favourable treatment outcomes in terms of bone loss, implant survival and soft tissue aspects, which are in line with values reported in other studies on single implants placed in the anterior maxilla (den Hartog et al. 2008).

Although not supported by our data, several other studies have demonstrated significantly more marginal bone loss around implants with a smooth neck compared with a rough neck (Hermann et al. 2000; Shin et al. 2006; Schwarz et al. 2008; Bratu et al. 2009; Nickenig et al. 2009; Stein et al. 2009). Also, it has been reported that retention elements, such as microthreads or grooves, could decrease marginal bone resorption (Shin et al. 2006; Lee et al. 2007; Nickenig et al. 2009). Because these studies mainly focused on posterior tooth replacements or were non-clinical of origin, it is questionable whether these results can be extrapolated to our findings. For instance, Nickenig et al. (2009) compared smooth and rough implants for restor-

Table 2. Changes in marginal bone level and marginal soft tissue level at implant and tooth sides from baseline to 18 months

Variable	Baseline† – T _{6m}			T _{6m} – T _{18m}			Baseline† – T _{18m}		
	Smooth (n = 30)‡	Rough (n = 31)	Scalloped (n = 31)	Smooth (n = 30)‡	Rough (n = 31)	Scalloped (n = 30)§	Smooth (n = 30)‡	Rough (n = 31)	Scalloped (n = 31)
Marginal bone level changes (mm)									
Mesial of implant	-0.96 ± 0.76	-0.79 ± 0.62	-1.84 ± 0.93*	-0.13 ± 0.45	-0.13 ± 0.4	-0.16 ± 0.58	-1.1 ± 0.83	-0.91 ± 0.66	-2.01 ± 0.74*
Distal of implant	-1.15 ± 0.82	-0.81 ± 0.76	-1.7 ± 0.98*	-0.13 ± 0.47	-0.09 ± 0.41	-0.3 ± 0.46	-1.27 ± 1.09	-0.9 ± 0.77	-2 ± 1.01*
Mesial tooth side	-0.23 ± 0.45	-0.25 ± 0.38	-0.3 ± 0.5	-0.01 ± 0.25	0.03 ± 0.28	0.02 ± 0.25	-0.24 ± 0.5	-0.17 ± 0.4	-0.28 ± 0.5
Distal tooth side	-0.20 ± 0.42	-0.18 ± 0.34	-0.29 ± 0.44	0.02 ± 0.28	-0.03 ± 0.42	0.02 ± 0.24	-0.17 ± 0.44	-0.29 ± 0.5	-0.27 ± 0.54
Implant bone loss (%)¶									
≤ 1 mm	47.9	62.9	18*	96.1	100	94.2	41.3	56.5	12.3*
1–2 mm	37.5	33.9	38	3.9	0	5.8	47.8	38.7	35.1
≥ 2 mm	14.6	3.2	44	0	0	0	10.9	4.8	52.6
Marginal soft tissue level changes (mm)									
Mesial implant papilla				0.12 ± 0.44	0.19 ± 0.29	0.27 ± 0.47			
Distal implant papilla				0.14 ± 0.35	0.35 ± 0.52	0.24 ± 0.43			
Mid-facial of implant				-0.09 ± 0.23	-0.09 ± 0.34	0.03 ± 0.22			
Mesial tooth	-0.14 ± 0.31	-0.13 ± 0.38	-0.19 ± 0.23	-0.10 ± 0.26	-0.09 ± 0.25	-0.02 ± 0.25	-0.24 ± 0.5	-0.22 ± 0.36	-0.21 ± 0.36
Distal tooth	-0.14 ± 0.39	-0.33 ± 0.51	-0.37 ± 0.53	0.02 ± 0.23	0 ± 0.3	0.1 ± 0.21	-0.12 ± 0.44	-0.33 ± 0.36	-0.28 ± 0.44
Pocket depth (mm)									
Mesial of implant				3.45 ± 0.87	3.03 ± 0.89	3.8 ± 1.24*	3.34 ± 1.2	3.19 ± 0.91	4.42 ± 1.18*
Distal of implant				3.41 ± 1.05	3.5 ± 0.82	3.67 ± 0.99	3.24 ± 0.79	3.81 ± 1.28	4.63 ± 1.13*
Mid-facial of implant				3.34 ± 0.72	3.07 ± 0.74	3.47 ± 0.97	3.1 ± 0.82	3.32 ± 0.79	3.65 ± 0.92*
Proximal of teeth¶	2.2 ± 0.57	2.03 ± 0.51	2.11 ± 0.5	2.18 ± 0.37	1.92 ± 0.49	1.92 ± 0.39	2.15 ± 0.41	1.99 ± 0.6	1.99 ± 0.65
Mid-facial of teeth	1.27 ± 0.39	1.37 ± 0.39	1.45 ± 0.44	1.29 ± 0.39	1.4 ± 0.53	1.28 ± 0.37	1.24 ± 0.32	1.37 ± 0.34	1.37 ± 0.39

Plus-minus values are means ± SD. T_{6m}, 6 months post-implant placement; T_{18m}, 18 months post-implant placement.

†After implant placement for bone levels, before implant placement for soft tissue levels and probing pocket depths.

‡One implant was lost.

§One patient did not attend follow-up visit T_{6m}.

*P < 0.05, between-group comparison.

¶Mesial and distal sides combined.

ing missing mandibular molars. They reported that from implant placement to 2 years thereafter, the rough implant neck with grooves was superior to the smooth neck in reducing radiographic marginal bone loss (mean bone loss 0.5 vs. 1.1 mm, standard deviation not reported, however). We found 0.9 ± 0.57 mm radiographic bone loss around the moderately rough implant neck and 1.19 ± 0.82 mm around the smooth implant neck.

In our study, all implants were placed at a 3 mm depth from the implant shoulder to the buccal and cervical aspect of the prospective clinical crown. All implants were levelled with the alveolar bone crest so that the whole implant neck was covered with bone (in some cases, an additional augmentation procedure was performed to cover the implant neck). It has been found that the position of the implant–abutment interface relative to the bone crest at the time of implant placement is a significant factor for marginal bone loss (Hermann et al. 2000; Brogini et al. 2006; Jung et al. 2008). An inflammatory reaction at the implant–abutment interface due to microbial leakage seems to be a major factor for this bone loss. A more apical position of the implant–abutment interface will increase the inflammatory reaction and will induce more marginal bone loss. Because in our study, the implant–abutment interface was closely related to the bone crest, possibly surface roughness or grooves could not prevent bone loss then.

Other factors might be also important in preventing bone loss. It has been suggested that besides surface roughness and grooves, a conical internal implant–abutment connection combined with a non-matching implant and abutment diameter favour marginal bone preservation (Wennstrom et al. 2005; Jung et al. 2008; Cochran et al. 2009). It seems that by reducing the diameter of the abutment, the implant–abutment interface and thereby the inflammatory reaction will be displaced further away from the bone, resulting in less marginal bone loss. Furthermore, an internal conical connection has been associated with a more stable connection possibly leading to less bacterial leakage and a better stress distribution (Hansson 2003; Coelho et al. 2008; Cochran et al. 2009).

We found significantly more radiographic marginal bone loss around the scalloped implant neck compared with the other implants with common flat platforms. To date, only case reports and cases series have been published addressing the outcome of scalloped implants (Mitrani et al. 2005; Nowzari et al. 2006; Kan et al. 2007; McAllister 2007; Noelken et al. 2007). Unfortunately, no other clinical trials on the scalloped implant have been published. Since case series are highly susceptible to bias, results

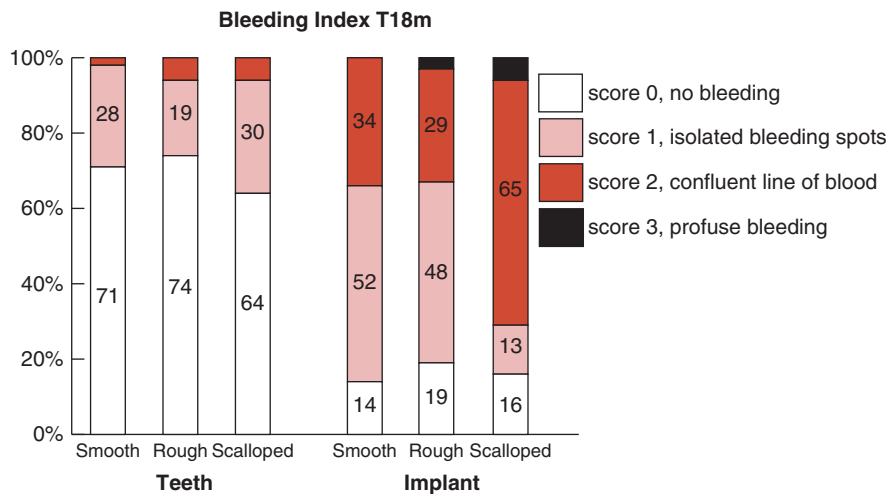


Fig. 3. Frequency distribution of bleeding index scores of implants and adjacent teeth at 18 months after implant placement.

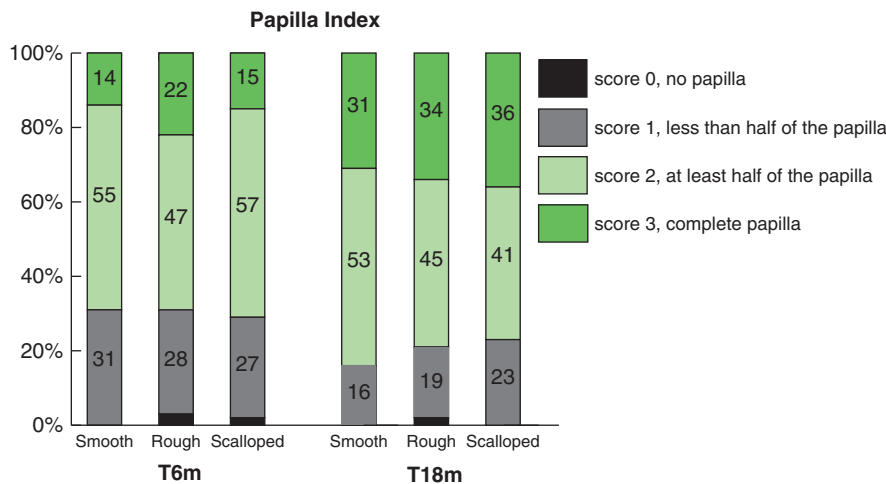


Fig. 4. Frequency distribution of papilla index scores at 6 and 18 months after implant placement.

Table 3. Outcome of multiple regression analysis

	B	SE B	β
Step 1			
Constant	2.01	0.13	
Type of implant			
Scalloped vs. Rough	-1.12	0.18	-0.62*
Scalloped vs. Smooth	-0.83	0.18	-0.46*
Step 2			
Constant	1.93	0.52	
Type of implant			
Scalloped vs. Rough	-1.07	0.18	-0.61*
Scalloped vs. Smooth	-0.94	0.18	-0.52*
Augmentation before implant surgery	-0.02	0.16	-0.02
Implant-tooth distance	0.2	0.11	0.17
Type of definitive crown	-0.15	0.15	-0.09
Age	-0.01	0.01	-0.14
Gender	0.12	0.15	0.07

$R^2 = 0.33$ for Step 1; $\Delta R^2 = 0.06$ for Step 2 ($P > 0.05$).
 SE, standard error.
 * $P < 0.05$.

of these studies should be interpreted with caution. When placed in healed extraction sites, the mean radiographic bone loss ranged from 1.5 to 2.1 mm (SDs around 1 mm) between implant placement and 12 months thereafter (Nowzari et al. 2006; Kan et al. 2007; McAllister 2007). These values were found for the original version of the scalloped implant with a 1.5 mm smooth collar. We observed a mean bone loss of 2 ± 0.77 mm around the scalloped neck after 18 months, although it was equipped with a moderately rough surface and grooves, which could favour marginal bone preservation.

We do not have a proper explanation for the finding that the scalloped implant showed more radiographic bone loss than the other study groups. One reason might be that peri-implant bone is mainly formed in a horizontal plane. As a result, bone at the proximal side of the implant might tend to be lost to equilibrate the more apical level of the mid-facial and mid-palatal peri-implant bone crest. Another reason could be inferred from a biomechanical point of view. Too much stress at the implant neck after loading, and shear stresses in particular, induces initial marginal bone resorption (Oh et al. 2002; Schrotenboer et al. 2008). We hypothesize that the stress distribution from the scalloped implant to the bone might be unfavourable and too high, leading to the amount of marginal bone loss as was observed during the first evaluation period. In this context, the complex connection between implant and abutment could play a role. However, stress models of scalloped implants are lacking. We do not feel that the radiographic analysis had shortcomings in detecting the small and less dense proximal bone peak around the scalloped implant, as has been suggested in some studies (Wohrle 2006; McAllister 2007). In this view, the clinical observation of deeper probing pocket depths can be adduced.

As was expected from other studies (Cardaropoli et al. 2006; den Hartog et al. 2008; Meijndert et al. 2008; Bratu et al. 2009; Nickenig et al. 2009), the most extensive radiographic marginal bone loss was observed during the first evaluation period (i.e., from implant placement to T_{6m}). During the next 12 months (at T_{18m}), only little marginal bone loss was noticed. This is consistent with the stable level of the mid-facial peri-implant mucosa as measured during the second evaluation period. The level of the papilla, however, was not stable but gained some height. Expressed in papilla index scores, this resulted in higher scores at T_{18m} compared with T_{6m} for all implant groups. This phenomenon has been reported in several single-implant studies reporting comparable papilla index scores (Jemt & Lekholm 2003; Schropp et al. 2005a; den Hartog et al. 2008; Meijndert et al. 2008). Neither from

these studies nor from the current study could this phenomenon be validly explained.

Within the whole study population, the changes in marginal peri-implant bone level were not correlated with the volume of the papilla expressed in papilla index scores neither with the facial PML compared with the contralateral tooth. At T_{18m} , the scalloped group did not show lower volume of the papilla expressed in papilla index scores and no higher discrepancies in PML than observed in the other study groups. With respect to the volume of the papilla, it should be realized that the bone level at the adjacent teeth may play a significant role. It is known that the level of the papilla is highly related to the bone level next to the adjacent teeth (Choquet et al. 2001; Kan et al. 2003; Romeo et al. 2008). We observed only little radiographic marginal bone loss at the adjacent teeth in all study groups. This prominent role of the adjacent teeth may also apply to the preservation of the PML. Besides, for this variable, the soft tissue level before implant placement could be more relevant to the future PML while the future PML is to a lesser degree related to the amount of marginal bone loss around the implant neck. All implants were placed in healed extraction sites, one-third of which were augmented. This might have had a significant effect on the level of the PML before implant placement.

It could have been more precise to compare the total amount of bone loss after 18 months with the changes in PML as measured on the standardized photographs. However, these changes can only be measured accurately after placement of

the definitive crown (i.e. T_{6m}) because thereafter the actual PML is established. After T_{6m} , only minor marginal bone loss and a concordant change in PML were observed. Because the most bone loss already had occurred during the first evaluation period, the true effect of bone loss on the PML might have been missed.

We measured deeper pocket depths around the scalloped implants together with higher bleeding scores at T_{18m} compared with the other study groups. These values increased significantly within the scalloped group during follow-up, despite only a little amount of marginal peri-implant bone loss. As described by Schou et al. (2002), even a mild marginal inflammation is associated with a deeper penetration of the probe. This might be a reason that deeper pockets depths were measured at T_{18m} , without observing a concordant loss of marginal bone loss. Furthermore, inflammation-induced swelling of the peri-implant mucosa might have resulted in an increased pockets depth ("pseudo-pocket"). Although there is no evidence showing a correlation between pocket depth and the presence of or absence of active peri-implant disease (Schropp et al. 2005b; Heitz-Mayfield 2008), it has been shown that with an increasing pocket depth, an environment is created for periodontal pathogens (Rams et al. 1984; Heydenrijk et al. 2002). We therefore believe that peri-implant pocket depths should be limited and remain stable over time to facilitate healthy peri-implant tissues. The long-term influence of increased pocket depth and bleeding on marginal bone levels needs further study as it applies to the interaction between marginal bone loss and pocket formation.

In conclusion, it was found that there were differences between anterior single implants with a 1.5 mm smooth neck, a moderately rough neck with grooves and with a scalloped moderately rough neck with grooves in preserving marginal bone as measured on radiographs. This effect could be attributed entirely to the implants with a scalloped neck, showing significantly more marginal bone loss than the other implant designs studied. Furthermore, deeper probing pockets depths and more bleeding were observed around the scalloped implants. Post-hoc analyses revealed no differences between the implants with a smooth neck and implants with a moderately rough neck with grooves in preserving marginal bone, and no differences in survival and soft-tissue aspects. Besides, these implants showed favourable results in agreement with what has been established in other studies on anterior single implants. We therefore suggest the use of either an implant with a 1.5 mm smooth neck or an implant with a moderately rough neck with grooves for replacement of a single missing anterior tooth as there seems at least no additional beneficial effect of the scalloped implant design for single implants placed in the anterior maxilla.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Supporting information in accordance with the CONSORT Statement 2001 checklist used in reporting randomized trials.

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